Comparison of 2% lidocaine infiltration and eutectic mixture of local anesthetics cream application before spinal needle insertion for pain reduction and assessment of maternal satisfaction levels in women undergoing cesarean section at a tertiary care setup in Pakistan: a randomized controlled trial

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Background: This study aimed to compare two analgesic pretreatment techniques for assessing pain reduction before spinal needle insertion and the subsequent patient satisfaction levels in pregnant female patients undergoing cesarean sections.

Methods: Sixty pregnant female patients scheduled for elective cesarean section under spinal anesthesia were randomly assigned to two groups. The Lidocaine group received local skin infiltration with 2% lidocaine pretreatment before spinal needle introducer insertion, whereas the eutectic mixture of local anesthetics (EMLA) group received EMLA (lidocaine 2.5% and prilocaine 2.5%) cream pretreatment for at least 30 min before spinal needle introducer insertion. Subjective and objective pain scores, procedure duration, number of attempts, maternal satisfaction, and decisions regarding future numbing procedures and regional anesthesia were assessed.

Results: The demographic characteristics of the patients were similar between groups. The mean visual analogue scale pain score was significantly lower in the EMLA group compared to the lidocaine group (P < 0.05). Additionally, the objective pain score was significantly lower in the EMLA group (P < 0.05). The duration of spinal block placement was significantly longer in the lidocaine group than in the EMLA group (P < 0.05). The number of attempts to perform the spinal block placement was similar in both groups. However, women in the EMLA group expressed greater overall satisfaction than those in the lidocaine group (76.7% vs. 20.0%, P < 0.05).

Conclusions: Analgesic pretreatment with EMLA cream is superior to local skin infiltration with lidocaine in pregnant patients undergoing elective cesarean section under spinal anesthesia.

Keywords: Analgesics; Anesthesia, Spinal; Anesthetics, local; Cesarean section; Lidocaine; Lidocaine, prilocaine drug combination; Pregnancy.
INTRODUCTION

The prospect of undergoing surgery is widely acknowledged as a significant trigger of anxiety in patients scheduled for cesarean section. One of the primary sources of anxiety and fear in this population is the anticipation of perioperative pain and discomfort associated with needlestick pain, particularly during the administration of spinal anesthesia [1].

For many decades, lower segment cesarean sections (LSCS) have been preferentially performed worldwide under regional anesthesia because of the numerous benefits it provides to both the mother and baby. In many medical centers, local infiltration of lidocaine or other anesthetics into subcutaneous tissues is a common practice for alleviating needlestick pain during spinal anesthesia. However, whether infiltration analgesia offers any advantages over a straightforward puncture without analgesia remains uncertain.

There are no universally accepted recommendations for the administration of local infiltration analgesia to the skin and subcutaneous tissue before spinal anesthesia, and its application varies among institutions [2]. Notably, the subcutaneous infiltration of local anesthetics can be painful [3]. Furthermore, during subcutaneous local anesthetic infiltration, patients often experience discomfort and may adjust their positions, making the subsequent insertion of the spinal introducer into the pre-anesthetized space more challenging.

Eutectic mixture of local anesthetics (EMLA) is a combination of lidocaine and prilocaine that has been effectively employed to alleviate needlestick pain. Several studies in the pediatric population have shown that the EMLA cream is effective in reducing pain during lumbar punctures [4,5]. However, there is a limited body of research conducted on adults that specifically analyzes the effectiveness of the EMLA cream in reducing pain during spinal anesthesia placement in various elective surgical procedures [2,6,7]. Kim et al. [8] evaluated the analgesic efficacy of topically applied EMLA before skin puncture for spinal or epidural anesthesia in non-pregnant patients scheduled for operations across various anatomical regions, including the lower abdominal, perineal, and lower extremities. Our study provides valuable insights into the application of EMLA in a pregnant patient population who underwent LSCS.

Pregnant female patients undergo numerous physiological changes and significant mental and emotional shifts that can influence their perception of pain. It has also been observed that depression and anxiety are highly prevalent during pregnancy, both of which, in turn, affect pain perception [9,10]. Consequently, the perception of pain in pregnant patients differs significantly from that of non-pregnant patients undergoing elective surgery.

We conducted this study to compare two analgesic pretreatment techniques, 2% lidocaine infiltration and EMLA, before spinal needle introducer insertion for pain reduction and to assess the maternal satisfaction level in patients undergoing LSCS under spinal anesthesia.

MATERIALS AND METHODS

This study was conducted at the Aga Khan University Hospital, Karachi, Pakistan which is a tertiary care hospital. This study was approved by the Ethics Review Committee of the hospital (2019-1791-4842) and registered at www.clinicaltrials.gov (NCT04050059). This study adhered to the Consolidated Standards of Reporting Trials (CONSORT) statement. The trial was conducted in compliance with International Conference on Harmonization-Good Clinical Practice (ICH-GCP).

This study included 18–45 years old pregnant patients, scheduled to undergo elective LSCS under spinal anesthesia. The exclusion criteria included patients with a body mass index (BMI) > 35 kg/m², any contraindication to spinal anesthesia, spinal deformities, refusal to receive regional anesthesia, history of back surgery, or confirmed allergy to local anesthetics.

Written informed consent was obtained from each patient before surgery in the preoperative area, and a copy of the informed consent was provided to the patient.

In this randomized controlled trial, non-probability consecutive sampling was performed. Patients were randomly assigned to one of the two groups (30 in each group) using a sealed opaque envelope. Each envelope contained one of the following two paper slips: 2% lidocaine (xylocaine 2%, Barrett Hodgson Private Limited) infiltration or EMLA (5 g tube, Aspen Pharma Trading Limited) application. The envelopes were opened in the preoperative area, and the intervention was assigned to a consultant or senior resident (year three and above). The envelopes were prepared using a computer-generated randomization table. The intervention was performed by the primary anesthesiologist and senior resident anesthesiologist in the operating room, both of whom were not involved in the study.
In the EMLA group, the patients were directed to sit with the back flexed in the preoperative area, and three potential spaces were marked. EMLA cream was applied to these preselected spaces, and the area was covered with a Tegaderm transparent film dressing (3M). The application of the EMLA cream lasted for at least 30 min before spinal needle insertion [7].

In the operating room, maintenance fluid was administered via an intravenous cannula which was inserted in the ward. Monitoring, including electrocardiogram, non-invasive blood pressure and SpO2, was commenced before the spinal anesthesia procedure. A blanket was provided to the patients to cover them from the front, and only the back was exposed. Patients were instructed to maintain a sitting position with their backs flexed. The Tegaderm dressing was removed and excess EMLA cream was wiped off in a preselected space with clean gauze. Hexi-prep spray (2% chlorhexidine and 70% isopropyl alcohol) was applied to the skin for disinfection. Spinal anesthesia was induced using a Pencan (B. Braun Medical Inc.) 25G pencil-point spinal needle via a 20G introducer by a senior resident (year 3 or above) or an anesthesia consultant who was not involved in the study. The objective pain score was recorded by another resident who was not involved in the study during spinal needle insertion using a five-point categorical pain scale (1 = no pain, 2 = mild flinch, 3 = wince, 4 = yelp, 5 = pulled away) [11]. The objective scoring assessor was standing in front of the patients and blinded to the spinal anesthesia procedure performed at the back. Immediately before spinal needle insertion, the anesthesiologist provided a hand signal to the objective pain score assessor to observe and record the objective pain score.

The subjective pain score was recorded immediately after the spinal needle was removed from the patient’s back. A visual analog scale (VAS) was used to assess the patient’s pain which comprised of a 10-cm line with the left end representing “no pain” and the right end representing “worst imaginable pain.” The patient was asked to put a vertical mark on the line to indicate the level of pain intensity. Maternal satisfaction, based on a Likert scale (5 = very satisfied, 4 = satisfied, 3 = neither satisfied nor dissatisfied, 2 = dissatisfied, 1 = very dissatisfied), was also asked from the patients immediately after the end of the spinal anesthesia procedure. All data were recorded by a resident anesthesiologist who was not involved in the study.

The number of times the introducer was inserted in intervertebral space till the free flow of cerebrospinal fluid was achieved via the pencil-point needle was considered as an attempt. Each new skin puncture made using a spinal introducer needle was counted separately. However, redirecting the needle without making a new skin puncture was not considered an additional attempt. Patients with more than three attempts were excluded from the study.

In the 2% lidocaine group, Hexi-prep spray (2% chlorhexidine and 70% isopropyl alcohol) was used for disinfection. After implementing aseptic measures, 3 ml of 2% lidocaine was infiltrated into the skin and subcutaneous tissue of the preselected space using a 27 gauge, 1.5 inches long needle. Spinal anesthesia was induced in the preselected space by a senior resident or an anesthesia consultant who was not involved in the study. Data were recorded in a manner similar to that described above. Patients with more than three attempts were excluded from the study.

Adverse events were monitored in the operating room by the primary anesthesiologist and documented in Proforma. The primary investigator was responsible for the follow-up of any adverse events, and the costs of managing these complications were covered by hospital insurance.

The primary outcome of the study was the pain score assessed immediately after the spinal anesthesia procedure, and the maternal satisfaction level was assessed using the Likert scale mentioned above.

The secondary outcome was the duration of the spinal anesthesia placement procedure (calculated from the time of insertion of the spinal introducer needle in the intervertebral space until the time the spinal needle was removed from the patient’s back), number of attempts, decision regarding the selection of regional anesthesia, and choice of the same numbing procedure for future surgeries by the patient.

Sample size calculation was based on a previous study in which the mean standard deviation of the pain score was 1.35 (0.8) in the local anesthetic infiltration group [2]. A sample size of 25 patients in each group was required to detect a 50% reduction (0.67 on VAS) in the mean pain score, which was considered clinically significant with 90% power and 5% type I error using a one-tailed test. To minimize any effect of data loss, we assessed 62 patients for eligibility, of which 60 were found to be eligible after application of the exclusion criteria. They were then recruited (30 patients in each group) for this study.

Data were analyzed using Statistical Package for Social Science version 19.0 (SPSS Inc.). The mean and standard deviation were reported for normally distributed quantita-
tive observations and analyzed using an independent sample t-test. The median (1Q, 3Q) was estimated for non-normally distributed quantitative variables and analyzed using the Mann-Whitney U test. Qualitative point estimates were reported in terms of frequency and percentage and analyzed using the chi-square test or Fisher’s exact test. Statistical significance was set at $P < 0.05$.

**RESULTS**

A total of 62 participants were initially assessed for eligibility, of which two were excluded. Among them, one participant did not meet the inclusion criteria, and another declined to participate in the study. Following this, a total of 60 pregnant female patients undergoing elective LSCS were enrolled in the study after providing informed written consent (Fig. 1). Of these, 30 patients each were randomly allocated to the 2% lidocaine and EMLA groups. The demographic data are presented in Table 1 and were found to be comparable, with no significant differences observed between the two groups in terms of age, weight, height, and BMI.

The mean VAS pain score was significantly lower in the EMLA group than in the Lidocaine group (estimated difference, 1.6; 95% confidence interval [CI], 0.8–2.3; $P < 0.05$; Fig. 1.

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**Table 1.** Demographic Characteristics of Patients Involved in the Study (n = 60)

<table>
<thead>
<tr>
<th>Variable</th>
<th>EMLA (n = 30)</th>
<th>2% Lidocaine infiltration (n = 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>$31.53 \pm 5.47$</td>
<td>$30.80 \pm 4.85$</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>$69.05 \pm 10.21$</td>
<td>$67.97 \pm 9.95$</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>$155.75 \pm 5.27$</td>
<td>$155.55 \pm 6.26$</td>
</tr>
<tr>
<td>Body mass index (kg/m$^2$)</td>
<td>$28.38 \pm 4.21$</td>
<td>$27.99 \pm 3.12$</td>
</tr>
</tbody>
</table>

Values are presented as mean $\pm$ SD. EMLA: eutectic mixture of local anesthetics. Sample t-tests and n (%) were analyzed using the chi-square test.

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**Fig. 1.** Diagram classifying the flow of the study participants through each stage of the randomized trial. CONSORT: Consolidated Standards of Reporting Trials, BMI: body mass index.
Objective pain scores in terms of pain intensity (wince, yelp/pulled away) were significantly lower (P < 0.05) in the EMLA group than in the lidocaine group (Fig. 3).

The median duration of the procedure was significantly longer in the lidocaine group than in the EMLA group (estimated difference, 0.74; 95% CI, 0.50–1.00; P < 0.05). However, the number of attempts were similar in both the groups (Table 2). All patients expressed their willingness to receive regional anesthesia for future surgeries, if the option was available. At the end of the spinal anesthesia procedure, the patients in the EMLA group were more satisfied than those in the lidocaine group (76.7% vs. 20.0%; P < 0.05), as shown in Table 2. No adverse events were reported for either pre-treatment drugs.

**DISCUSSION**

In contemporary obstetric care, regional anesthesia is the preferred method for cesarean sections because of its numerous advantages over general anesthesia [12]. The Royal College of Anesthetists audit guidelines recommend that >95% of elective cesarean sections should be performed under regional anesthesia [13].

Despite the benefits, parturients often decline spinal anesthesia for cesarean sections primarily because of their fear of needlestick pain. A survey by Gajraj et al. [14] revealed that 28% of obstetric patients refused regional anesthesia because of fear of needles. The prospect of having a needle inserted into the back during a procedure that the patient

![Fig. 2. Comparison of mean VAS pain score between groups. VAS: visual analogue scale, EMLA: eutectic mixture of local anesthetics, CI: confidence interval.](image)

![Fig. 3. Comparison of objective pain in term of intensity between groups. EMLA: eutectic mixture of local anesthetics.](image)
can neither observe nor control is of significant concern to them and justifiably causes apprehension [1].

One of the most negative aspects of a patient’s experience with regional anesthesia is the pain experienced during skin puncture; numbing the puncture site can significantly improve the patient’s comfort level [15]. Although the pain perception of the patient may be highly subjective and at times, abstract, anxiety states and fear can increase the susceptibility to pain [16]. In this study, we evaluated patients’ pain perception using both subjective and objective methods. This dual approach was adopted because pain is a complex and individualized emotional experience and its interpretation is contingent on personal experience and one’s ability to express it. Pain scales are effective tools for the subjective gauging of pain intensity. However, verbal narratives of pain can be fake, repressed, and can deliberately mislead. Therefore, objective behavioral assessment of pain can complement subjective measures and provide a more comprehensive understanding of a patient’s pain experience [17].

Our findings indicate a significant reduction in pain scores with EMLA pretreatment compared to 2% lidocaine infiltration before spinal needle insertion in pregnant patients. This aligns with the results of trials in non-pregnant patients that have consistently reported the superior efficacy of EMLA over local anesthetic infiltration for dermal punctures [6,7,18]. Our study in pregnant patients further supports the superiori ty of EMLA cream application, as both subjective and objective pain scores were significantly lower in the EMLA group.

The time required for the EMLA cream to become effective differs depending on the site of treatment. Studies have shown that EMLA can become effective within 25 min on the face and thighs [19]. Bjerring et al. [20] reported that the EMLA cream reached a maximum depth of approximately 5 mm after 90–120 min. They noted that the effectiveness of the EMLA cream depends on factors such as cutaneous blood flow and the thickness of the epidermis and dermis, which influence the diffusion distance of the drug. Sharma et al. [7] applied EMLA for an average of 51 min before the induction of spinal anesthesia in female patients undergoing postpartum tubal ligation and reported its superiority over 1% lidocaine infiltration. In our study, we applied EMLA cream in pregnant female patients for at least 30 min and found that this duration was adequate for achieving a significant reduction in pain scores. However, further studies are required to determine the optimal EMLA cream application time on the back of pregnant female patients.

The time required for spinal anesthesia induction was also significantly prolonged in the 2% lidocaine infiltration group compared with that in the EMLA group. Although the EMLA application required a 30-min waiting period for effectiveness, this was performed in the preoperative area, which saved operating room time. The elective obstetric operation list was not delayed at any point during the study because the patients were called well before the time in the preoperative area. One of the reasons, which can be attributed to the prolonged spinal anesthesia procedure time in the lidocaine infiltration group, is the additional step of local infiltration of the skin with lidocaine and subsequent waiting for an adequate amount of time for it to act.

**Table 2. Comparison of Parameters Between Groups (n = 60)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>EMLA (n = 30)</th>
<th>2% Lidocaine infiltration (n = 30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of procedure (min)</td>
<td>0.75 (0.5, 1.00)</td>
<td>1.54 (1.12, 2.00)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Number of attempts</td>
<td></td>
<td></td>
<td>0.601</td>
</tr>
<tr>
<td>1</td>
<td>27 (90.0)</td>
<td>26 (86.7)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3 (10.0)</td>
<td>3 (10.0)</td>
<td></td>
</tr>
<tr>
<td>&gt; 2</td>
<td>0 (0.0)</td>
<td>1 (3.3)</td>
<td></td>
</tr>
<tr>
<td>Will you select the same numbing intervention for spinal anesthesia again?</td>
<td></td>
<td></td>
<td>0.020</td>
</tr>
<tr>
<td>Yes</td>
<td>30 (100.0)</td>
<td>25 (83.3)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0 (0.0)</td>
<td>5 (16.7)</td>
<td></td>
</tr>
<tr>
<td>Maternal satisfaction</td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>23 (76.7)</td>
<td>6 (20.0)</td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td>7 (23.3)</td>
<td>24 (80.0)</td>
<td></td>
</tr>
</tbody>
</table>

Values are presented as median (1Q, 3Q) or number (%). EMLA: eutectic mixture of local anesthetics. Analyzed by the Mann-Whitney U test and n (%) analyzed by the chi-square test.
In both the EMLA and lidocaine infiltration groups, the first-attempt success rates for spinal needle insertion were not clinically significant, with rates of 90% and 86.7%, respectively. All patients agreed to receive spinal anesthesia for future surgeries if provided with the option. This aligns with the findings of Rhee et al. [21], who reported that a previous successful attempt at spinal anesthesia increased the likelihood of patients accepting future spinal anesthesia.

Furthermore, the potential acceptance of the same numbing intervention for future procedures was clinically significant in the EMLA group (100.0%) compared with the lidocaine infiltration group (83.3%). While all patients expressed satisfaction with both numbing procedures, the EMLA group had a significantly higher number of patients who reported being more satisfied than the lidocaine group. This could be attributed to the avoidance of needlestick pain associated with local infiltration when EMLA is used to numb the area, which significantly reduces fear and anxiety.

Our study had few limitations. First, we excluded all patients with BMI > 35 kg/m². While EMLA cream application for 30 min was adequate in lean patients owing to less subcutaneous tissue in the back, more studies are required to assess the adequate EMLA application time in pregnant patients with a higher BMI and to determine whether our results can be extrapolated to them.

Second, an objective pain score assessment of subjective outcomes can be abstract and assessor dependent. To reduce the risk of bias, the same individual served as the objective pain assessor in all cases, remained blinded to the ongoing intervention, and was signaled at the exact time to assess the objective pain score.

Third, we used a Pencan (B. Braun Medical Inc.) 25G pencil-point spinal needle via a 20G introducer for the placement of spinal anesthesia. This choice was driven by the limited number of options available at our institution. Our experience with this spinal needle indicated a post dural puncture headache rate of < 1% and a failure rate of 2.4% [22].

However, EMLA creams have certain limitations. It is expensive, not readily available in some countries, and requires considerable time to take effect. Consequently, it cannot be used in emergency procedures. In such cases, infiltration of a local anesthetic such as 2% lidocaine may be considered to maximize the comfort level of patients.

In conclusion, EMLA is an effective technique for reducing the pain associated with spinal needle insertion during the induction of spinal anesthesia in pregnant patients. It is a simple, well-accepted approach, offering superior analgesic efficacy compared to 2% lidocaine infiltration and is associated with higher patient satisfaction when used in pregnant patients. Although EMLA requires a longer onset time, this issue can be addressed by applying it to the preoperative area or ward. To further validate and consolidate our results, additional multicenter studies with larger sample sizes are required. Moreover, further research in pregnant patients is essential to determine the optimal duration of EMLA to achieve full effectiveness.

FUNDING
None.

CONFLICTS OF INTEREST
No potential conflict of interest relevant to this article was reported.

DATA AVAILABILITY STATEMENT
The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

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REFERENCES


